UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' JOINT MOTION TO EXCLUDE
OPINIONS OF EDWARD H. KAPLAN, M.D.

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Pursuant to Federal Rules of Evidence 104, 702, and 703, Defendants' Executive Committee, on behalf of the undersigned Defendants in this litigation, submits this Memorandum of Law in Support of Defendants' Joint Motion to Exclude Opinions of Dr. Edward H. Kaplan ("Motion").

INTRODUCTION

Plaintiffs in this litigation are asking the Court to establish a medical monitoring protocol for a proposed class of wholly *asymptomatic* individuals in the United States who have allegedly reached a certain level of exposure to nitrosamine impurities, purportedly from taking valsartan containing drugs ("VCDs"). In support of this effort, they rely exclusively on the unreliable opinions of Edward Kaplan, M.D.

Dr. Kaplan opines that a monitoring program is appropriate and necessary for individuals who took valsartan allegedly containing nitrosamine impurities and who allegedly reached the Lifetime Cumulative Threshold ("LCT")—a threshold of exposure to NDMA and/or NDEA calculated by Plaintiffs' counsel and purportedly based on the opinions of experts who did not themselves calculate any LCTs.[1] His proposed program calls for annual monitoring of all individuals in the purported class (and subclasses) using a litany of screening tests—some invasive, some

[1] A copy of Dr. Kaplan's Expert Report (hereinafter, "Kaplan Rep." or "Report"), is attached to the accompanying Certification of Victoria Lockard, Esq. ("Lockard Cert.") as **Exhibit A**.

subjecting the individual to annual exposure to radiation, and one not even approved by the FDA. Specifically, Dr. Kaplan calls for all individuals in the class to be exposed to annual low dose CT scans (radiation), as well as more invasive procedures such as a colonoscopy at least every five years. He also proposes fecal testing and annual blood tests, including prostate-specific antigen ("PSA") tests for males regardless of age, and the Galleri® test, an experimental blood test designed to screen for various cancers that has not been approved by the FDA. Although Dr. Kaplan treats cancer patients in his medical practice, he has never designed a monitoring program to screen for cancer; rather, his opinion was made for this litigation.

Plaintiffs have failed to satisfy their burden of showing that Dr. Kaplan's opinions are based on a reliable methodology or that he is qualified to offer them. Accordingly, his opinions should be excluded in their entirety.

First, Dr. Kaplan's opinions are inadmissible because he failed to: (1) apply a reliable methodology to determine whether the monitoring he proposes would benefit VCD users; and (2) reliably analyze whether the benefits of his proposed medical monitoring plan outweigh its potential risks to each proposed class member. Dr. Kaplan vaguely purports to rely on medical literature and his experience for his opinion that medical monitoring is necessary for valsartan patients, but he has not identified any relevant literature or experience to substantiate his opinions, punting

entirely to Plaintiffs' other experts on key opinions. He also admittedly has no basis to conclude that his proposed medical monitoring program will lead to a reduction in mortality and morbidity. Further, Dr. Kaplan disregards the risks posed by medical monitoring of asymptomatic patients and instead simply assumes, without any scientific basis, that the proposed monitoring would benefit all proposed class members despite their individualized medical histories. Such *ipse dixit* falls far below the standard of reliability required for an expert opinion to satisfy Fed. R. Evid. 702 and *Daubert.*

Second, Dr. Kaplan is not qualified to testify about the propriety of a proposed medical monitoring regime. Dr. Kaplan's education, training, specialized knowledge, and clinical or research experience are all focused entirely on treating patients who have cancer, not on designing programs for the early detection of cancer. Moreover, Dr. Kaplan has never recommended the testing he proposes in this lawsuit in his clinical practice. Rather, his opinions were developed solely for this litigation. In short, Dr. Kaplan is not qualified to design a public medical monitoring program for a class of asymptomatic individuals, or to opine that Plaintiffs in this litigation require such monitoring.

For all of these reasons, discussed further below, the Court should exclude Dr. Kaplan's medical monitoring opinions.

FACTUAL BACKGROUND

Plaintiffs' proffered expert, Dr. Edward Kaplan, is a board-certified medical oncologist. (Kaplan Rep. 1.) As set forth in Dr. Kaplan's Report, Plaintiffs' counsel requested that Dr. Kaplan "evaluate[] the question of whether and to what extent medical monitoring would be appropriate for [putative class members] who used valsartan containing drugs ("VCDs" or "valsartan")" that allegedly contained N-nitrosodimethylamine ("NDMA") and N-nitrosodiethylamine ("NDEA"). (*Id.*) Dr. Kaplan claims that he "reviewed scientific literature, regulatory documents and other documents, and applied [his] knowledge, education and experience in order to outline and summarize the issues and approach to organizing a screening and monitoring program for class members exposed to VCDs that were contaminated with NDMA and/or NDEA." (*Id.*) Dr. Kaplan concedes, however, that he has not investigated (or even read about) whether exposure to NDMA or NDEA reasonably necessitates medical monitoring. (Kaplan Dep. 42:18-43:5, 100:2-13.)[2] In fact, Dr. Kaplan has no specialized expertise as to either nitrosamine or the medications at issue in this litigation. Dr. Kaplan has never published or given a lecture on NDMA, NDEA, or valsartan (*id.* at 39:6-40:8), and the entirety of his writing and research in this area is limited to his Report in this case (*id.* at 40:9-20).

[2] A copy of the transcript from Dr. Kaplan's January 19, 2022 deposition (hereinafter, "Kaplan Dep."), is attached to the accompanying Lockard Cert. as **Exhibit B**.

Dr. Kaplan nonetheless opines that "there exist diagnostic tests that can mitigate the risks of developing cancer faced by the class of people because of their exposure to contaminated valsartan (who meet the LCT), that this program is different than the one that would have been prescribed in the absence of that particular exposure and increased risk, and that it is reasonable and necessary." (Kaplan Rep. 6.) Dr. Kaplan's proposed medical monitoring program includes the following screening for asymptomatic individuals: (1) specialized annual physical examination by an internist or family practitioner; (2) specialized laboratory testing, including Galleri®, Cologuard® (or similar fecal testing for colon cancer); and (3) "periodic testing," including colonoscopy (every five years); upper endoscopy (every five years or based on symptoms); and annual low-dose CT chest scan. (*Id.* at 4-6.)

Dr. Kaplan has never developed a public medical monitoring program. (Kaplan Dep. 44:14-18; *see also id.* at 106:23-107:5 ("Q. And, Doctor, have you ever—have you ever crafted a medical monitoring plan such as this for litigation before? A. No. Q. Have you ever published on medical monitoring? A. I have not.").) Nor does he screen his own patients in the manner he proposes for this litigation. (*Id.* at 85:7-13.) Dr. Kaplan also lacks specific data on whether his proposed monitoring program would reduce mortality in the putative class members. (*Id.* at 97:21-98:14.) And he cannot identify any scientific literature that supports annual

screening of asymptomatic patients exposed to NDMA or NDEA. (*Id.* at 100:2-13.)

LEGAL STANDARD

When experts are "critical to class certification," their testimony is subject to "rigorous analysis" under "the standard set out in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)." *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015) (citation omitted). The importance of this gatekeeping function "'cannot be overstated.'" *Sardis v. Overhead Door Corp.,* 10 F.4th 268, 283 (4th Cir. 2021) (quoting *United States v. Barton*, 909 F.3d 1323, 1331 (11th Cir. 2018) (internal modification omitted). "The proponent of expert testimony has the burden of establishing its admissibility by a preponderance of the evidence." *Ctr. City Periodontists, P.C. v. Dentsply Int'l, Inc*., 321 F.R.D. 193, 202 (E.D. Pa. 2017).

The Third Circuit has explained that Rule 702 embodies a trilogy of restrictions on expert testimony: "qualification, reliability, and fit." *Calhoun v. Yamaha Motor Corp., U.S.A.*, 350 F.3d 316, 321 (3d Cir. 2003) (internal quotations omitted).

In evaluating whether expert testimony satisfies the requirements of Rule 702, the Court "must make certain that [the] expert . . . employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *see also Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) ("[T]he courtroom is

not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."). Under Rule 702, the expert's opinions must be the "product of reliable principles and methods" that have been "reliably applied . . . to the facts of the case." Fed. R. Evid. 702. This requires a review of both "an expert's methodology and the application of that methodology." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 792 (3d Cir. 2017). "[A]ny step that renders [an expert's] analysis unreliable . . . renders [his or her] testimony inadmissible." *Id.* at 797 (citation omitted); *see Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000) (proponent of testimony must show that the "reasoning or methodology underlying the testimony is scientifically valid and . . . that reasoning or methodology properly can be applied to the facts in issue") (quoting *Daubert*, 509 U.S. at 592-93); *In re Pharmacy Benefit Managers Antitrust Litig.*, No. 03-4730, 2017 WL 275398, at *17 (E.D. Pa. Jan. 18, 2017) ("The reliability prong 'applies to all aspects of an expert's testimony: the methodology, the facts underlying the expert's opinion, and the link between the facts and the conclusion.'") (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 291 (3d Cir. 2012)).

A court should not admit "evidence that is connected to existing data only by the ipse dixit of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997); *see also Montgomery County v. Microvote Corp.*, 320 F.3d 440, 448 (3d Cir. 2003) (because "conclusions and methodology are not entirely distinct from one another .

. . a 'court may conclude that there is simply too great a gap between the data and the opinion proffered.'") (quoting *Joiner*, 522 U.S. at 146). Nor should a court permit one expert to merely "parrot or act as a mouthpiece for other experts' opinions, without independent verification of those opinions." *Edmond v. Plainfield Bd. Of Educ.*, No. 11-cv-2805 (KM) (JBC), 2018 U.S. Dist. LEXIS 158980, at *14 (D.N.J. Sept. 13, 2018) (internal quotations omitted); *see also In re TMI Litig.*, 193 F.3d 613, 716 (3d Cir. 1999) ("unblinking reliance" by an expert on another's opinions "demonstrates that the methodology he used to formulate his opinion was flawed under *Daubert* as it was not calculated to produce reliable results"), *as amended*, 199 F.3d 158 (3d Cir. 2000).

In addition, the proponent of expert testimony must establish that the expert is qualified "to render an opinion" based on his or her "specialized expertise." *In re Hum. Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 655 (D.N.J. 2008) (citation omitted). Although qualification is interpreted liberally, the Third Circuit recognizes that an expert who "may be generally qualified" may nevertheless "lack qualifications to testify outside his area of expertise." *Calhoun*, 350 F.3d at 322. "While the background, education, and training may provide an expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions." *Id*.

Finally, plaintiffs must establish that the testimony "will assist the trier of

fact" in understanding issues relevant to the case. *Id.*, at 321; *see* Fed. R. Evid. 702(a). This means that the testimony must have "a valid scientific connection" to, or "fit," the pertinent inquiry in the lawsuit. *Daubert*, 509 U.S. at 591-92; *Calhoun*, 350 F.3d at 321. "The issue of fit 'is one of relevance and expert evidence which does not relate to an issue in the case is not helpful.' . . . The standard for fitness is 'not that high' but is 'higher than bare relevance.'" *In re Hum. Tissue Prod Liab. Litig.*, 582 F. Supp. 2d at 657 (internal citations omitted).

ARGUMENT

I. DR. KAPLAN'S OPINIONS ARE NOT BASED ON A RELIABLE METHODOLOGY.

Expert opinions regarding medical monitoring will be admitted only if they are grounded in "scientifically valid reasoning or methodology"—i.e., "studies or peer-reviewed literature which suggest[] that the testing and monitoring he recommends should be performed[.]" *In re Ingram Barge Co.*, 187 F.R.D. 262, 265-266 (M.D. La. 1999) (excluding medical monitoring opinions under *Daubert*; claiming that medical surveillance was "fairly standard care in cases of exposure to other carcinogenic agents" was not a valid substitute for "studies or peer-reviewed literature" supporting conclusory claim of necessity); *see also, e.g.*, *McManaway v. KBR, Inc.*, No. H-10-1044, 2012 WL 13059744, at *15 (S.D. Tex. Aug. 22, 2012) (agreeing with defendant that expert's medical monitoring opinion "is unreliable because [he] has failed to provide medical authority to support it"); *Anderson v. Dow*

Chem. Co., No. CIV.A.02-12RET-SCR, 2006 WL 6545465, at *4 (M.D. La. Mar. 2, 2006) (excluding expert's opinions regarding need for medical monitoring where the opinions "lack[ed] sufficient data, explanation, or methodological analysis of the relevant facts in this case to be considered reliable or relevant"), *aff'd*, 255 F. App'x 1 (5th Cir.).

Because "the medical monitoring process itself entails substantial health risks," *In re Paoli R.R. Yard PCB Litig.*, No. 86-2229 et al., 2000 WL 274262, at *8 (E.D. Pa. Mar. 7, 2000), an expert "must first establish that the probable usefulness of the[] [proposed] tests outweighs the attendant risks prior to subjecting a healthy person to screening," *id.* Accordingly, the failure to conduct "[s]uch a risk/benefit analysis" is a telltale sign of an unreliable medical monitoring opinion. *See, e.g.*, *id.* at *9 ("by prescribing numerous screening tests without considering the information that is critical to an assessment of their necessity, Dr. Sherman's approach creates a great potential for error in the screening process.").

As explained below, Dr. Kaplan's opinions are unreliable under these principles because he lacks a reliable, scientific basis for opining that: (1) the proposed monitoring would be beneficial to proposed class members; or (2) the supposed usefulness of the proposed tests outweighs the risks posed by the surveillance.

A. Dr. Kaplan Lacks A Reliable, Scientific Basis To Conclude That The Monitoring He Proposes Would Be Beneficial To The Proposed Members of the Medical Monitoring Classes.

First, Dr. Kaplan did not independently analyze whether exposure to valsartan requires the annual cancer screenings he proposes. Rather, he relies exclusively on Plaintiffs' other experts for the fundamental notion that all members of the proposed class—i.e., those who satisfy Plaintiffs' LCT threshold—require the panoply of invasive medical tests he proposes in his report. (*See* Kaplan Dep. 67:17-68:12 (Q. "What's your basis for that opinion [that all proposed class members should be screened for nine different cancers]? A. My basis for the opinion is the evidence provided that suggests that these cancers are at increased risk of patients that have had exposure to that carcinogen and the levels they had exposure to, so they deserve to be monitored for those. Q. And again that's based on the four Plaintiffs' experts that you referred to? A. Correct.").) Federal law is clear, however, that one expert "may not parrot or act as a mouthpiece for other experts' opinions," *Edmond*, 2018 U.S. Dist. LEXIS 158980, at *14; rather, "[i]t is only when the expert undertakes some independent investigation of the underlying opinions that his testimony may be considered reliable." *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 275 (E.D. La. 2014); *see also In re TMI*, 193 F.3d at 716 (affirming the exclusion of an expert witness in part because the expert relied on the opinions of other experts

without independently validating them). Further, "[o]ne very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995.

Dr. Kaplan conceded that he has never investigated or even read about whether exposure to NDMA or NDEA reasonably necessitates medical monitoring, either prior to or in connection with this litigation. (Kaplan Dep. 100:2-13.) Rather, he merely surmises that relevant literature probably exists "because the reports that have come out were based on it" (referring to reports from Plaintiffs' other experts) and the FDA "withdrew the drug [] in a rapid manner."[3] (*Id.*) In addition, while Dr. Kaplan purportedly tailors his proposed medical monitoring recommendations to patients "who have a level of exposure [to NDMA or NDEA] greater than or equal to the LCT" (Kaplan Rep. at 3), he admitted that this is not a term he has ever used or seen outside of this litigation, and that his understanding of its meaning is simply an assumption based on "his knowledge of the English language" (Kaplan Dep. 75:14-76:14). Further, Kaplan himself admitted that he is not aware of any clinically

[3] This statement is incorrect. Defendants voluntarily recalled the valsartan products from the market; the FDA did not "withdraw" the products from the market.

available test to monitor LCT. (*Id.* at 85:19-86:1). Presumably for this reason, Dr. Kaplan essentially conceded that he has no basis upon which to conclude that Defendants should bear the cost of his sweeping proposed medical monitoring—i.e., that exposure to NDMA or NDEA from sources ***other than*** affected valsartan could not independently cause a patient to reach the LCT. Kaplan testified that he is unaware of any way to determine how a patient reaches the LCT, whether from exposure to NDMA through diet, environment, valsartan with nitrosamine impurities, or other sources. (*Id*. at 77:16-18, 82:20-83:5.) He simply believes it is "not likely" that a patient's exposure would reach the LCT without exposure to affected valsartan based on what Plaintiffs' other experts in the litigation have said.[4] (*Id.* at 83:8-19.) However, such "unblinking reliance on those experts' opinions[] demonstrates that the methodology [Dr. Kaplan] used to formulate his opinion was flawed under *Daubert*" and should be excluded. *In re TMI*, 193 F.3d at 716.

Dr. Kaplan's medical monitoring opinions are also inherently unreliable because he lacks a valid scientific basis for concluding that the monitoring program

[4] Notably, Plaintiffs' other experts have not endorsed or opined upon the specific LCTs proffered by Plaintiffs' counsel to define their proposed medical monitoring classes. Although Plaintiffs cite to the general causation reports of Drs. Madigan and Panigrahy, neither expert submitted a supplemental expert report for class certification and neither has offered any opinion regarding LCTs. Thus, Dr. Kaplan has offered opinions based on an unfamiliar term, which he does not understand, using numbers crafted only by Plaintiffs' counsel without a supporting expert opinion.

he proposes would improve health outcomes in proposed class members. *See In re Paoli*, 2000 WL 274262, at *8 (excluding medical monitoring opinions where, *inter alia*, the "extensive battery of periodic screening tests" had "no known medical benefit in the treatment of any condition and there is no recognized medical purpose in performing such tests on asymptomatic persons"). Dr. Kaplan assumes that the recommended testing is "reasonable and necessary" for all class members (Kaplan Rep. at 4), based on his vague and subjective impression of "what medically makes sense" (Kaplan Dep. 65:4-9). But Dr. Kaplan admitted at his deposition that he has no actual data on whether his proposed monitoring program would reduce mortality in the putative class members. (Kaplan Dep. 97:21-98:14.) Further, Dr. Kaplan was unable to cite to any published literature that supports annual screening of asymptomatic patients exposed to NDMA or NDEA, much less the specific battery of tests he proposes. (*Id.* at 100:2-13.) Dr. Kaplan also admits that he has never previously recommended such a screening program, either to his own patients or otherwise. (*Id.* at 44:14-18.)

These multiple failures are particularly glaring given the pronouncement by the FDA following the voluntary 2018 recall that patients should ***continue*** taking their valsartan-containing medications[5] and the determination by the Committee for

[5] *See* Statement on the Agency's Ongoing Efforts to Resolve Safety Issue with ARB Medications (Aug. 28, 2019), https://www.fda.gov/news-events/press-

Medicinal Products for Human Use that there is ***no*** evidence to support "cancer screening or additional monitoring of patients exposed to N-nitrosamines" in valsartan.[6] *See Allgood v. Gen. Motors Corp.*, No. 102CV1077DFHTAB, 2006 WL 2669337, at *31 (S.D. Ind. Sept. 18, 2006) (excluding expert's opinion regarding medical monitoring where he failed to "consider[] such [government agency] sources," which "is highly relevant to whether [he] used a method in developing the medical monitoring program that comports with generally accepted practices"). Accordingly, Dr. Kaplan's opinions are not supported by any "medical authority," *McManaway*, 2012 WL 13059744, at *15, rendering those opinions quintessential *ipse dixit* and therefore inadmissible.

In short, Dr. Kaplan has not performed any independent, scientific investigation capable of reliably determining that the medical monitoring program he proposes would benefit the proposed class members. For this reason alone, his opinions are not based on a reliable scientific methodology and should be excluded.

B. Dr. Kaplan's Opinions Are Unreliable Because He Did Not Assess Whether The Potential Risks Of The Proposed Monitoring Outweigh Any Purported Benefit.

Second, Dr. Kaplan's opinions are also unreliable because he did not consider

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announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications (last visited April 22, 2022).

[6] European Medicines Agency, Lessons Learnt From Presence of N-nitrosamine Impurities in Sartan Medicines, at p. 9, June 23, 2020, attached to the accompanying Lockard Cert. as **Exhibit C.**

the risks presented by medical monitoring of asymptomatic patients, much less determine whether such potential harm is outweighed by the supposed usefulness of his proposed tests. *In re Paoli* is instructive. In that case, the plaintiff sought medical monitoring because of his exposure to polychlorinated biphenyls ("PCBs"), used in transformers of train cars that the plaintiff serviced and maintained in the Paoli Railroad yard. *In re Paoli*, 2000 WL 274262, at *1. After the Third Circuit clarified Pennsylvania law governing medical monitoring and held that the trial court had abused its discretion in excluding the plaintiff's medical monitoring expert in a related trial, the district court excluded the testimony again, reasoning that "by prescribing numerous screening tests without considering the information that is critical to an assessment of their necessity, [the expert's] approach create[d] a great potential for error in the screening process." *Id.* at *9. In particular, the court explained that the plaintiff's expert ignored that the "medical monitoring process itself entails substantial health risks," including both physical injuries from "invasive" testing and "emotional risks to a patient's health" (e.g., "anxiety and behavior changes that often accompany a patient labeled with a disease"). *Id.* at *8. Given these fundamental deficiencies, the court determined, the plaintiff's expert had failed to "establish that the probable usefulness of th[e] proposed tests outweigh[ed] the attendant risks[.]" *Id*.

The same is true here. Although Dr. Kaplan's Report outlines a bevy of tests

and procedures that he claims should be performed on an annual or more frequent basis, Dr. Kaplan did not consider whether the potential risks of those tests would outweigh the harm for each proposed class member. Procedure risk is a "very real concern" with Dr. Kaplan's proposed tests, particularly for older patients (i.e., the bulk of patients who used valsartan-containing medications), because these patients face an "increased risk of complications" from invasive screening methods such as endoscopy and biopsy, as well as potentially unnecessary radiation exposure from imaging.[7] Further, cancer screenings can adversely impact patients by generating "anxiety, overdiagnosis, and complications from invasive cancer workups." (Ex. D, at 8.)

Notably, Dr. Kaplan conceded that there are numerous risks associated with the screening procedures he recommends in this case. (*See, e.g.*, Kaplan Dep. 71:1-11 (agreeing that a patient who has had a prior perforation would be at a significant risk of injury as a result of a colonoscopy); *id.* at 73:6-74:7 ("There are risks to everything. A blood draw, the needle could break off, you could get infection, you could have pain.").) Indeed, the existence of these risks is precisely why, as Dr. Kaplan put it, "***every person has to be evaluated individually***" before the screening proposals he is recommending are prescribed for any given patient. (*Id.* at 73:20-

[7] *See* Jan. 12, 2022 Expert Report of Ursina R. Teitelbaum at pp. 5, 16, 18, a true and correct copy of which is attached to the accompanying Lockard Cert. as **Exhibit D**.

74:7 ("Someone that has other conditions of the colon . . . like severe diverticulitis or diverticulosis may not be a good candidate for some of the screening. So, of course, every person has to be evaluated individually.") (emphasis added); *id.* at 126:12-22 ("My plan is a guideline . . . and it's up to the individual practitioner to . . . decide based on the individual patient what is appropriate for them.").) But Dr. Kaplan did not even purport to perform such an evaluation for anyone in the proposed classes, much less all proposed class members.[8]

In sum, Dr. Kaplan has failed to undertake a "risk benefit analysis," offering his opinions regarding a host of disparate medical monitoring tests "without considering the information that is critical to an assessment of their necessity." *In re Paoli*, 2000 WL 274262, at *8. These opinions reflect Dr. Kaplan's own subjective say-so, are "scientifically unsound and [are] not accepted by the medical community." *Id.* For these reasons too, the Court should exclude his opinions as unreliable.

* * * * * *

Dr. Kaplan evidently expects that his monitoring program will be accepted on his say-so, with no supporting research, analysis, or meaningful explanation. His

[8] Follow-up care after screening is performed is an additional area in which patient-specific factors must come into consideration, including the patient's age, desires, and comorbidities. Notably Dr. Kaplan's Report does not mention the next steps—whether medication, radiation, surgery, or something else—that he believes are required if a test returns a positive result.

insistence that his program be adopted at face value, without methodological support, is directly contrary to well-settled law on expert reliability, which requires a demonstrated association between the data and the expert's opinion. "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146; *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 608 (D.N.J. 2002) (same). Kaplan failed to analyze whether his recommendations make sense for these Plaintiffs. His opinions are patently unreliable and should be excluded.[9]

II. DR. KAPLAN IS NOT QUALIFIED TO DESIGN A PROPOSED MEDICAL MONITORING PLAN.

Dr. Kaplan's opinions should also be excluded because he is not qualified to offer them. This is so both because the need for a public medical monitoring program—and the appropriate elements of such a program—lies outside his field of expertise as a practicing clinical oncologist, and because he lacks any experience related to valsartan or to nitrosamines.

[9] Moreover, Dr. Kaplan's opinions are not a fit to this case because they would not be helpful to the factfinder. Without a reliable basis for his opinion, and particularly given his lack of understanding of the underlying basis for the proposed medical monitoring program, Dr. Kaplan cannot assist the factfinder in making any determination as to disputed material facts.

"While [an expert's] background, education, and training may provide [the] expert with general knowledge to testify about general matters, more specific knowledge is required to support more specific opinions." *Calhoun*, 350 F.3d at 322. In keeping with this principle, courts have prohibited witnesses from testifying to the design of medical monitoring programs absent specific expertise on the issue. *See Allgood*, 2006 WL 2669337, at *29 (excluding medical monitoring opinions from professor of environmental health science and biomedical sciences; "[a]lthough Dr. Carpenter's experience studying the health effects of PCBs is extensive, he is not qualified to testify as to the proper components and cost of a medical monitoring program"); *Arias v. DynCorp*, 928 F. Supp. 2d 10, 25 (D.D.C. 2013) (excluding medical monitoring expert who was a specialist in occupational and environmental medicine in part because "the plaintiffs offere[d] no explanation as to how Dr. Wolfson's education qualifies him to offer such testimony").

This Court should do the same. Dr. Kaplan has purported to design a medical monitoring program for all asymptomatic individuals who have taken enough affected valsartan to reach the LCT, recommending annual testing for all nine types of cancer that are the subject of Plaintiffs' proposed medical monitoring class. These opinions are untethered to Dr. Kaplan's professional work.

Dr. Kaplan is a practicing oncologist. He treats patients diagnosed with cancer—not patients who are cancer free and asymptomatic, but who have been

briefly exposed to a potential carcinogen. Notably, Dr. Kaplan has never concluded that "any patient's cancer was caused by NDMA or NDEA" at any point in his career. (Kaplan Dep. 96:9-17.) In addition, Dr. Kaplan admitted that he has never recommended the specialized screening tests he proposes here to his own patients, including those who have been exposed to ***known*** human carcinogens, such as tobacco.[10] (*Id.* at 110:18-111:5.) Dr. Kaplan also conceded that he only recently learned of the Galleri® test he recommends in his Report and has ordered it only "a few times" in his practice. (*Id.* at 111:7-17.) Accordingly, he lacks the specific knowledge required to support his opinion that the medical monitoring program he proposes is appropriate for asymptomatic patients allegedly exposed to nitrosamines in VCDs. *See Calhoun*, 350 F.3d at 322.

This is especially true given that Dr. Kaplan lacks any experience with or expertise in either the VCDs at issue or the nitrosamines they allegedly contained. As Dr. Kaplan has acknowledged, he has never published or given a lecture on NDMA, NDEA, or valsartan (Kaplan Dep. 39:6-40:8), and the entirety of his writing and research in this area is limited to his Report in this case (*id.* at 40:9-20). He also has no opinion on the alleged carcinogenicity of NDMA or NDEA, aside from

[10] NDMA and NDEA are not classified by the International Agency for Research on Cancer as "known human carcinogens," but rather as "probable human carcinogens." Defendants' experts have thoroughly explored the distinction between these classifications in their reports and deposition testimony.

simply assuming that Plaintiffs' other experts are correct in their position that the affected valsartan puts patients at risk of cancer. According to Dr. Kaplan, this assumption is necessary to "justify and create [his] program." (*Id.* at 102:20-103:16.)

Put simply, Dr. Kaplan has no specific knowledge regarding, or experience designing, public monitoring programs, let alone specific knowledge of the drug and alleged exposure in this case. For this reason, too, his opinions should be excluded.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court exclude Dr. Kaplan's opinions in their entirety.

Dated: April 26, 2022

Respectfully Submitted:

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CERTIFICATE OF SERVICE

I, Kate Wittlake, an attorney, hereby certify that on April 26, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

/s/ Kate Wittlake
Kate Wittlake